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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,922	01/20/2004	Cary J. Reich	WMFUS-5879(1)CIP	2159

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EXAMINER	
MOHAMED, ABDEL A	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/761,922	REICH ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/25/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

ACKNOWLEDGMENT OF IDS AND STATUS OF THE CLAIMS

1. The information disclosure statement (IDS) and Form PTO-1449 filed 02/25/04 are acknowledged, entered and considered. Claims 1-29 are present for examination.

With respect to the IDS, the references cited therewith on Form PTO-1449 are not provided in the instant application. However, as *per* Applicant's request, since the cited references were considered previously in parent application Serial No. 09/330,315; pursuant to 37 CFR § 1.98(d), all the references cited in Form PTO-1449 in this application have been considered and signed as requested by Applicant.

OBJECTION TO THE SPECIFICATION

2. The continuity data of this application should be updated in the specification.

OBJECTION TO THE CLAIM

3. Claim 2 is objected in the recitation "gelatin matris". It is believed to be typographical error. Appropriate correction is required.

CLAIMS REJECTION-35 U.S.C. § 112 2nd PARAGRAPH

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 are indefinite in failing to recite as to the function or use of the dried hemoactive material (i.e., it is not clear what the dried hemoactive material is supposed to do).

Claim 11 is indefinite in the recitation various species of cross-linked protein polymers by reciting "wherein the cross-linked polymer is a protein selected from the group comprising gelatin, collagen, albumin....."because it is not clear if Applicant intends a Markush format. If Applicant intends to use a Markush format, then, the Office recommends the use of the phrase "....selected from the group consisting....." in listing species to ensure the Markush group is "closed".

Claim 13 is indefinite in the recitation "A method as in claim 1" because claim 1 is not directed to method, rather is directed to a dried hemoactive material. Appropriate correction is required.

Claim 27 is indefinite and incomplete in failing to recite how the material is applied to a wound site for inhibiting bleeding. Is the material applied topically or parenterally by injection or by other means. Appropriate clarification is required.

Claim 28 is also indefinite and confusing in failing to recite how the material is exposed to patient blood. There is no mechanism recited in the claim how the active agent is delivered to a patient. Appropriate clarification is required.

Claim 29 recites the limitation "particles of a cross-linked biologically compatible polymer" in line 5. There is insufficient antecedent basis for this limitation in claim 29.

HEADING FOR NONSTATUTORY DOUBLE PATENTING

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

OBVIOUSNESS-TYPE DOUBLE PATENTING

6. Claims 1-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 6,706,690. Although, the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed invention (Serial No. 10/761,922) as claimed in independent claims 1 and 2 is directed to a dried hemoactive material which forms a hydrogel when exposed to blood comprising a cross-linked biologically compatible polymer and a non-cross-linked biologically compatible polymer, wherein the cross-linked biologically compatible polymer forms a hydrogel when exposed to blood and a non-cross-linked biologically compatible polymer dissolves (solubilize) when exposed to blood, and to a method for inhibiting bleeding. Similarly, claims 1-27 of '690 patent is directed substantially to a dried material which forms a hydrogel when exposed to blood comprising a cross-linked biologically compatible polymer and a non-cross-linked biologically compatible polymer, wherein the cross-linked biologically compatible polymer forms a hydrogel when exposed to blood at 37^0 C and a non-cross-linked biologically compatible polymer dissolves (solubilize) when exposed to blood, a plasticizer present in the non-cross-linked biologically polymer and to a method of inhibiting bleeding, a method for delivering an active agent to a patient and a method for making a material thereof.

Although, both inventions use the same procedure/process and components for hemoactive compositions methods for their manufacture and use. Thus, both inventions use substantially the same procedure/process and components for using a

dried (hemoactive) material which forms a hydrogel when exposed to blood comprising a cross-linked biologically compatible polymer and a non-cross-linked biologically compatible polymer, wherein the cross-linked biologically compatible polymer forms a hydrogel when exposed to blood and a non-cross-linked biologically compatible polymer dissolves (solubilize) when exposed to blood. Hence, both inventions are basically the same since they are made by the same procedure for the same purpose. Nevertheless, the only difference between the '690 patent claims and the claims of the instant application is the scope of the claims in which the '690 patent claims appear to be specific in scope because claims 1 and 2 of '690 patent are directed to additional limitation wherein a plasticizer is present in the non-cross-linked compatible polymer and the polymer dissolves in 15 minutes or less when exposed to blood (although, the presence of the plasticizer in cross-linked polymer and the degradation time are claimed in claims 4 and 9 of the instant invention, respectively). Furthermore, claim 2 of '690 patent has a limitation of exposure of the blood to 37^0 C. With respect to claim 13 of the instant invention, it appears to be typographical error because the claim depends on claim 1 which is not a method claim. Thus, the only difference between claim 13 of the instant invention and claim 11 of "690 patent is the preamble (i.e., A method as in claim 1 *versus* A material as in claim 1). Thus, the instant application claims are broadly directed to a hemoactive material without specifying the limitations incorporated in independent claim 1 and 2 of '690 patent which was claimed in dependent claims 4 and 9 of the instant invention, except for the temperature of claim 2 of '690 patent, which is a design choice.

Therefore, since both inventions are directed to a dried hemoactive material which forms a hydrogel when exposed to blood comprising a cross-linked biologically compatible polymer and a non-cross-linked biologically compatible polymer, wherein the cross-linked biologically compatible polymer forms a hydrogel when exposed to blood and a non-cross-linked biologically compatible polymer dissolves (solubilize) when exposed to blood, and to a method for inhibiting bleeding, a method for delivering an active agent to a patient and a method fro making hemoactive material thereof. Thus, both inventions use substantially the same processes and components for the same purpose; it is conventional and would be within the purview of ordinary skill in the art to use or adapt either the broader scope or the specific because both procedures use the same techniques for the same purposes.

Therefore, both inventions (i.e., both sets of claims) are an obvious variation of the other since substantially same procedure is used for the same purpose, and as such, one of ordinary skill in the art would envision both sets of claims as one invention and obvious variation of each other.

CONCLUSION AND FUTURE CORRESPONDANCE

7. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CAMPELL BRUCE can be reached on (571) 272 0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JON WEBER
SUPERVISORY PATENT EXAMINER

Mohamed/AAM
April 17, 2006